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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/700,687	02/14/01	BENBADIS	L 33339/206076

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HM22/0716

EXAMINER

DAVIS, R

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

07/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

09/700,687

Applicant(s)

BENBADIS ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspond ne address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 – 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism, *L. bulgaricus* (CNCM number I-1968) is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, a deposit of the microorganism may satisfy the requirements of 35 U.S.C. § 112. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. Moreover, because no taxonomic information appears in the specification, it is not clear what the microorganism actually is.

However, since a deposit **has** been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest

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Treaty **and** that **all** restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 – 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 – 10 are rendered confusing for reciting the phrase “characterized in that” because it does not clearly delineate what is included or excluded from the scope of the claims. The phrase does not clearly set forth the metes and bounds of the invention so that one in the art could practice the invention.

Claim 3 is confusing because it is narrative in nature and does not clearly point what applicant regards as the invention. It is not clear if the claim is further limiting claim 1, or is an independent claim drawn to a separate invention.

Claims 9 and 10 are rendered indefinite for reciting “can be” because it is not clear if the fermented dairy product must be obtained by the method of claim 6, or if it is optionally obtained by the method of claim 6 as the phrase fails to define whether the recited method actually occurs or not.

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Claim 10 is confusing for reciting "the fermented dairy". Applicant may prefer to insert "product" after the phrase to more clearly describe the invention.

*Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 – 7 and 9 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hottinger et al. (US 5,382,438).

Applicant claims a strain of *Lactobacillus bulgaricus* (*L. bulgaricus*), lacking beta-galactosidase activity wherein a nonsense mutation occurs in at least one coding sequence of the lactose operon wherein the coding sequence encodes beta-galactosidase and has been deposited with CNCM as I-1968. Applicant further claims a lactic ferment comprising at least one strain of *L. bulgaricus* further combined with *Streptococcus thermophilus* (*S. thermophilus*). Applicant finally claims a method for preparing a fermented dairy product comprising a step of fermenting milk, a lactic ferment comprising at least one strain of *L. bulgaricus* and at least one sugar, wherein the sugar is glucose, and a fermented dairy product obtained thereby, wherein the dairy product is yogurt.

Hottinger et al. teach a method of preparing yogurt wherein fermenting milk is inoculated with *S. thermophilus* and a lac- mutant strain of *L. bulgaricus*, wherein the *L. bulgaricus* has a

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deletion of at least part of the beta-galactosidase gene (abstract). Hottinger et al. further teach the *L. bulgaricus* mutant is incapable of fermenting lactose (or lacks beta-galactosidase activity) (col.3 line 9-11) and that glucose is added to the culture in order to modulated the acidification rate and postacidification in storage (col.3 line 14-16). Hottinger et al. disclose a known production of yogurt wherein *S. thermophilus* is combined with a strain of *L. bulgaricus* selected for its inability to ferment lactose (or lacking beta-galactosidase activity) wherein the starting milk must be supplemented with glucose (col.1 line 43-49).

The reference anticipates the claimed subject matter. Although the reference does not teach the CNCM number as claimed by applicant, the described characteristics of the mutant *L. bulgaricus* are taught, thus anticipated by, the reference (see col.5 line 11-25 and 39-53).

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Hottinger et al. (US 5,382,438) in view of Mainzer et al. (US 5,639,648).

Applicant claims a method for preparing a fermented dairy product comprising a step of fermenting milk, a lactic ferment comprising at least one strain of *L. bulgaricus* and at least one sugar, wherein fermentation is arrested without cooling the dairy product.

Hottinger et al. teach a method of preparing yogurt (a dairy product) wherein fermenting milk is inoculated with a lac- mutant strain of *L. bulgaricus* (abstract) and glucose (col.3 line 14-16).

Hottinger et al. do not teach the method wherein fermentation is arrested without cooling the product. However, one of ordinary skill in the art would have been motivated to do so because Mainzer et al. teach mutant *L. bulgaricus* organisms which are sensitive to (or decrease in activity or fermentation) conditions (abstract) such as pH (col.2 line 38-42). Mainzer et al. suggest that the pH sensitive strains used in the manufacture of fermented products (e.g. yogurt, col.1 line 40-44) arrests fermentation at certain pH levels, and is an alternative to refrigeration (or cooling) for decreasing the rate of acid formation (col.2 line 38-42). At the time of the invention, one of ordinary skill in the art would have been motivated by Mainzer et al. to arrest fermentation without cooling, with a reasonable expectation of success of preparing a fermented dairy product.

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Additional references not cited in this action have been listed in PTO-892 to establish the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); alt. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

July 13, 2001



**LEON B. LANKFORD, JR.**  
**PRIMARY EXAMINER**